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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,965	11/06/2000	Esmail Kiani-Azarbayjany	MLABS.018C3	8509

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EXAMINER

KREMER, MATTHEW J

ART UNIT PAPER NUMBER

3736

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/706,965

Applicant(s)

KIANI-AZARBAYJANY ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "the volume" in line 7 in which there is insufficient antecedent basis.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,151,516 to Kiani-Azarbayjany et al. ('516) in view of U.S. Patent 4,883,055 to Merrick. Claim 7 of '516 claims a "method of non-invasively monitoring venous blood oxygen saturation" which includes the steps of transmitting optical radiation, detecting the optical transmission, generating an output signal, and actively influencing a change in the volume of blood. It is obvious to one with ordinary skill in the art that a system would be required to carry out the method steps of Kiani-Azarbayjany et al. It is also within the skill level of one in the art to be able to construct a system that carries out the claimed method steps. For example, Merrick teaches a pulse oximeter which determines oxygen saturation that includes infrared and red lights, a photodetector, a signal processor, and a finger cuff for inducing a blood pulse. (column 1, lines 27-40 and column 2, lines 24-40 of Merrick). Such components would be required to carry out the method steps of Kiani-Azarbayjany et al. ('516). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct a system to carry out the claimed method steps of Kiani-Azarbayjany et al. ('516) since various components are required to carry out the method steps of Kiani-Azarbayjany et

al. and Merrick teaches such components. In regard to claim 1, claim 7 of '516 claims a "method of non-invasively monitoring venous blood oxygen saturation" which is narrower in scope than claim 1 of the instant application which is a system for "monitoring a blood constituent concentration". Claim 7 of '516 also claims a step of "actively influencing a change in the volume of blood in said fleshy medium in said field of view area according to a predetermined pattern in a manner that causes modulation of said output signal greater than modulation caused by the natural pulse" which is narrower in scope than claim 1 of the present application which includes an "active pulse inducement device which causes a periodic change in the volume of blood". Claim 7 of '516 also claims a step of "determining said venous blood oxygen saturation based upon said output signal" which is narrower in scope than claim 1 of the present application which includes a "signal processor responsive to said output signal to analyze said output signal to extract portions of said signal" for determining "the concentration of said constituent". The device of the combination which would carry out the claimed method steps of claim 7 of '516 would meet all the limitations set out in claim 1 of the present application. It would be obvious that one who is determining the venous blood oxygen saturation with the steps listed in claim 7 of '516 is actually determining the concentration of a blood constituent as recited in claim 1 of the instant application.

6. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,860,919 to

Kiani-Azarbayjany et al. ('919) in view of U.S. Patent 4,883,055 to Merrick. Claim 1 of '919 claims a "method of non-invasively determining an indication of a concentration of a blood constituent" which includes the steps of transmitting optical radiation, detecting the optical transmission, generating an output signal, and actively influencing a change in the volume of blood. It is obvious to one with ordinary skill in the art that a system would be required to carry out the method steps of Kiani-Azarbayjany et al. It is also within the skill level of one in the art to be able to construct a system that carries out the claimed method steps. For example, Merrick teaches a pulse oximeter which determines oxygen saturation that includes infrared and red lights, a photodetector, a signal processor, and a finger cuff for inducing a blood pulse. (column 1, lines 27-40 and column 2, lines 24-40 of Merrick). Such components would be required to carry out the method steps of Kiani-Azarbayjany et al. ('919). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct a system to carry out the claimed method steps of Kiani-Azarbayjany et al. ('919) since various components are required to carry out the method steps of Kiani-Azarbayjany et al. and Merrick teaches such components.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,883,055 to Merrick (cited by Applicant). Merrick discloses a pulse oximeter which measures oxygen saturation in arterial blood. (Abstract of Merrick). Merrick teaches a light source that emits a plurality of wavelengths and a photodetector. (claim 1 of Merrick). An artificially induced blood pulse is caused by finger cuff 10 (column 2, lines 24-40 of Merrick). Merrick also discloses a signal processor in the form of a computer. (column 1, lines 27-40 of Merrick).

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,007,4235 to Branstetter et al. Branstetter et al. discloses a pulse oximeter which measures oxygen saturation in arterial blood. (Abstract of Branstetter et al.). Branstetter et al. teaches a light source that emits a plurality of wavelengths, a photodetector, and a signal processor. (column 2, line 60 to column 3, line 27 of Branstetter et al.). An artificially induced blood pulse is caused by heating from warming LEDs (column 2, lines 33-47 of Branstetter et al.).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for


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the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
Assistant Examiner
Art Unit 3736
August 29, 2002



ERIC F. WINAKUR
PRIMARY EXAMINER